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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,970	08/06/2003	James A. Bianco	CELLTH 3.0-012	1243
530 7590 01/05/2007 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			EXAMINER TELLER, ROY R	
			ART UNIT	PAPER NUMBER
			1654	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/05/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/635,970	<b>Applicant(s)</b> BIANCO, JAMES A.	
	<b>Examiner</b> Roy Teller	<b>Art Unit</b> 1654	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 September 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/06</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This office action is in response to the reply, received 9/25/06.

Claims 1-20 are pending.

#### ***Information Disclosure Statement***

The information disclosure statement, received 12/4/06, is acknowledged. A signed copy is enclosed hereto.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Li et al (USPN 5,977,163) in view of Li et al (USPN 6,262,107).

The instant invention is drawn to a therapy for the treatment of cancer comprising administering to a patient in need thereof a polymer-taxane conjugate; wherein the the polmer of the polymer –taxane conjugate is poly-1-glutamate and the taxane of said polymer-taxane conjugate is paclitaxel; and one or more of a group comprising chemotherapeutic agents.

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Li et al. ('163) teaches compositions of paclitaxel formed by conjugating the paclitaxel to a polymer such as poly-L-glutamic acid, see, i.e., for example, abstract and claims. Li discloses that the present invention may be combined with a platinum drug (carboplatin or cisplatin- reading on the limitations of claims 13-20) see, i.e., for example, , column 3, lines 13-17.. Li discloses methods could be used to make polymer conjugates of other therapeutic agents, contrast agents, and drugs, including other anti-tumor or anti-cancer drugs. Li teaches such combinations are known in the art and such conjugation would be well within the skill of a routine practitioner of the chemical art, and as such would fall within the scope of the claimed invention, see i.e., for example, column 2, line 61- column 3, line 17. Other drugs that are used in combination with Taxol ( vinorelbine- reading on the limitations of claims 1-12). See, i.e., for example, '107 & '163 patents, column 3, lines 11-18.

Li et al. ('107) teaches compositions of paclitaxel formed by conjugating the paclitaxel to a polymer such as poly-L-glutamic acid, see, i.e., for example, abstract and claims. Li discloses that the present invention may be combined with a platinum drug (carboplatin or cisplatin- reading on the limitations of claims 13-20) see, i.e., for example, , column 3, lines 13-17. Li discloses methods could be used to make polymer conjugates of other therapeutic agents, contrast agents, and drugs, including other anti-tumor or anti-cancer drugs. Li teaches such combinations are known in the art and such conjugation would be well within the skill of a routine practitioner of the chemical art, and as such would fall within the scope of the claimed invention, see i.e., for example, column 2, line 61- column 3, line 17. Other drugs that are used in combination with Taxol ( vinorelbine- reading on the limitations of claims 1-12). See, i.e., for example, '107 & '163 patents, column 3, lines 11-18.

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From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claim invention because the '163 and '107 patents disclose that the paclitaxel formed by conjugating the paclitaxel to a polymer such as poly-L-glutamic acid may be combined with a platinum drug (carboplatin or cisplatin- reading on the limitations of claims 13-20)see, i.e., for example, '107 & '163 patents, column 3, lines 13-17. Other drugs that are used in combination with Taxol ( vinorelbine- reading on the limitations of claims 1-12). See, i.e., for example, '107 & '163 patents, column 3, lines 11-18. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Conclusion***

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RT  
1654  
12/13/06



  
ANISH GUPTA  
PRIMARY EXAMINER